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1999P-5332  
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Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

RE: FDA Request for Comment on Tentative Final Rule on Substances Affirmed as Generally Recognized as Safe: Menhaden Oil

Ladies and Gentlemen:

Omega Protein Corporation submits this letter in response to the request dated January 15, 2004 by the U.S. Food and Drug Administration for public comment on Docket No. 1999P-5332.

In June 1997, the FDA issued a final rule (62 FR 30751) affirming menhaden oil as GRAS as a direct human food ingredient with limitations on the maximum allowable levels in specific food categories. The FDA concluded that these limitations are needed to ensure that daily intakes of EPA and DHA from menhaden oil do not exceed 3.0 grams per person per day. In February 2002, the FDA published a proposed rule (67 FR 8744) in response to a citizen petition by the National Fish Meal and Oil Association to reallocate the uses of menhaden oil in food, while maintaining intake of 3 grams per person per day of EPA and DHA.

Omega Protein strongly believes and suggests to all users of menhaden oil, that the product be declared as "menhaden oil" on the ingredient label. "Menhaden Oil" is the common and usual name for this product.

Omega Protein also agrees with FDA that other sources of short-chain omega-3, such as flax seed, are outside the scope of the proposed rule. Menhaden Oil is a source rich in long chain omega-3 fatty acids, EPA and DHA, the most physiologically beneficial omega-3 fatty acids.

The menhaden industry has harvested menhaden as a source of fishmeal and oil for over 100 years. The fish is indeed, not considered edible in its entirety, due to its oily and bony nature. However, edible menhaden oil is highly refined to remove impurities and enhance stability, much like edible vegetable oils.

Omega Protein agrees with FDA that menhaden are safe. Menhaden are pelagic, short-lived surface feeders, feeding on phytoplankton and zooplankton. Menhaden are not predacious, and live to an average of three years. Therefore they do not have a high potential or

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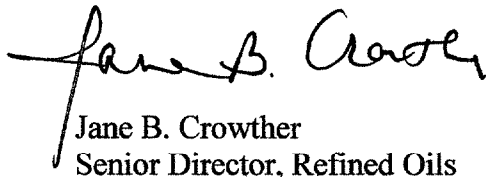
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likelihood of becoming contaminated. Contaminants such as mercury fall through the water column to the depths, away from menhaden. Also long-lived predacious fishes have the greatest potential to bio-accumulate mercury and other toxins due to consuming contaminated fish over the course of 10+ years.

Omega Protein supports FDA's conclusion that the GRAS certification as a direct human food ingredient will not have a significant impact on the menhaden population. Omega Protein disagrees with comments received by the agency that this action will result in "near extinction" of the menhaden population as shown by population decline of menhaden and the decline of game fish on the Atlantic Coast. According to the Federal agency tasked with the management of the menhaden resource, the Atlantic menhaden is not over-fished, nor is over-fishing occurring. The overall scientific status of the stock is considered "healthy", and has remained as such for many years. Concurrently, stocks of previously stressed Atlantic game fish such as striped bass achieved "Fully Recovered" status in the mid-1990s according to the ASMFC. Since that time, the striped bass population has continued to grow, and now reaches record numbers.

Omega Protein supports FDA in the decision to ensure the safe use of menhaden oil as long as the product is not used in combination with any other added oil that is a significant source of EPA or DHA. We would like to urge FDA to conduct a timely review of public comment and we support implementing a final rule as soon as possible to reallocate the uses of menhaden oil in food.

Very truly yours,



Jane B. Crowther  
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